



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

OCT - 8 1997

Sheldon A. Schooler, M.D.  
Woodland Farm Ltd.  
798 Spring Road  
Marathon, Wisconsin 54448-9986

0761 '97 DEC 16 P1:37

Dear Dr. Schooler:

This is in response to your letter of September 23, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Woodland Farm, Ltd. is making claims for the product "Physician's Choice Respiratory Herbal Dietary Supplement with Licorice Root:

Can Help:  
Cough  
Immune Function of:  
Sinuses  
Throat  
Lungs

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, mitigate, or cure a disease, namely coughs. This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make a claim of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.  
Acting Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

975-0163

LET 70

# WOODLAND FARM LTD

798 Spring Road  
Marathon, WI 54448-9986

September 23, 1997

0762 '97 SEP 30 10:37

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. St. SW  
Washington, DC 20204

## To Whom It May Concern:

Please find enclosed the document for notification related to a statement of nutritional support under section 403 (r) 6 §101.93 et al. Although the regulation provides for the elements of the notification, it does not provide for the format. Enclosed is my proposal. It is simple and concise.

We are currently in the process of redesigning all of our materials to take advantage of section 403 (r) §101.93 et al. to better inform the consumer. If any elements of the proposed label are objectionable, please notify us within 30 days of the specific objection and the specific reason(s), so that we can make the appropriate adjustments.

Reasonable substantiation has been established related to benefits and especially safety, before any of my products are marketed. It is my policy to personally review the world-wide medical research literature as a part of product development. Having been involved in biochemical medical research in the past, I feel I am reasonably qualified to evaluate the quality and accuracy of the literature I review. It is my purpose to provide beneficial, safe products of the best possible quality to the consumer. I, or members of my immediate family, use my products on a regular basis, and have done so for a number of years.

Sincerely,

Sheldon A. Schooler, M.D.  
Physician's Choice Herbal Products

P.S. This is the sixth of seven product notices to be sent.

IN THE UNITED STATES

FOOD AND DRUG ADMINISTRATION

OFFICE OF SPECIAL NUTRITIONALS

RECEIVED  
10/3/97

0763 '97 DEC 16 P1:37

Subject: Notification, Statement of Nutritional Support, as provided  
for in section 403 (r) (6) §101.93 et al.

Notification Mailing Date (Certified Mail): 9/24/97

Distributor: Woodland Farm, Ltd.  
798 Spring Rd.  
Marathon, Wisconsin 54448

Product Brand Name: Physician's Choice Respiratory

Dietary Ingredients: Ginseng, Glycyrrhiza(licorice root), Ophiopogon, Ginger  
root, and Bupleurum.

Statement(s) Attributable to Ingredient: Ginseng-Immune function; Licorice root-  
Cough(contributes to thinning of airway mucus to help reduce the discomfort caused  
by coughing).

Date of First Use In Commerce: 9/30/97

Actual Label Attached Below:

As per §101.93 (c), the undersigned certifies that the information contained in this notice is complete and accurate, and that the notifying firm has reasonable substantiation that the statement is truthful and not misleading.

Sheldon A. Schooler, M.D., President

Notification receipt date,  
Office of Special Nutritionals \_\_\_\_\_

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